REMARKS

I. Telephone Interview

Applicants wish to thank Examiner Fernandez for courtesies extended during a telephone interview of December 18, 2007.

II. Status of Claims

Claims 1-6 are pending, and stand rejected.

The listing of currently-pending claims is presented as a courtesy to the Examiner.

III. Claim Rejections under 35 U.S.C. § 103(a)

Claims 1-6 stand rejected as obvious over JP 56-131394 ("JP '394 "; 15-page translation of same attached at **Exhibit A**).

The Examiner contends that JP '394 discloses a method wherein 10 g of crude coenzyme Q_{10} (ubiquinone-10) are dissolved in a solution which was further treated with 20 mL of a 28% NH_4OH–MeOH mixture at 10°C for 20 minutes. The Examiner further contends the crude coenzyme Q_{10} can be considered to be a processed product of a culture of ubiquinone-10. The Examiner concludes that the aforementioned step meets all the requirements of step 1 of the instant claim 1.

The Examiner further contends that in the next step of JP '394, the NH_4OH–MeOH layer is discarded, and the remaining impurities (insoluble matter) are extracted a second time with 20 mL of 95% MeOH solution at 10°C for 20 minutes. The Examiner contends that this meets all the limitations of the instant steps 2 and 3, except for the temperature at which the resulting mixture is retained. The Examiner alleges that a purified coenzyme Q_{10} is recovered from this extraction; and, therefore, the insoluble matter must have been removed, and thus corresponds to the instant step 4; with the last step in '394 being a recrystalization from acetone.

The Examiner concedes that the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the final concentration of 50 to 100 v/v% of methanol solution in the total volume of the resulting mixture as reacted in the instant step 1, but argues that the solution of a specific volumetric ratio of methanol to the total resulting mixture would have been a routine matter of optimization, recognizing that the extraction of impurities would have been dependent on the concentration of methanol solution present in preparing the resulting mixture. Therefore, the Examiner concludes the limitations in the instant step 1 are obvious.

The Examiner also concedes that the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the temperature at which the resulting mixture is retained after the insoluble matter is treated with methanol solution as in the instant step 3, but argues that

the selection of a suitable temperature for retaining the mixture is a matter of routine optimization. Therefore, the Examiner concludes the limitations in the instant step 3 are obvious.

The Examiner also contends that it would be obvious to repeat the extraction steps by adding methanol to the coenzyme Q_{10}-containing solution after removal of insoluble matter, to achieve the result of purifying the coenzyme Q_{10}. The combination of methanol and coenzyme Q_{10}, the Examiner contends, is a methanol solution containing ubiquinone-10 meeting the requirements of instant step 5. Applicants respectfully traverse.

In our previous amendment, we had argued that steps 3, 4, and 5 produce a solution of ubiquinone-10 in methanol. However, the Examiner has taken the position that step 5, which recites "methanol solution containing ubiquinone-10" does not signify that ubiquinone-10 is dissolved in methanol. The definition of a solution is the mixing of a solid, liquid or gaseous substance (solute) with a liquid (the solvent) to form a homogeneous mixture (Grant & Hackh's Chemical Dictionary, 5th Edition, 1987, p. 541; attached as **Exhibit B**). Therefore, step 5, by definition, must be a homogeneous mixture, and therefore the ubiquinone-10 must be dissolved in methanol.

The Examiner further contends that our previous argument, that the invention involves the precipitation of ubiquinone-10, is not persuasive since there is no recitation of any precipitation

occurring. Precipitation is defined as the process of producing or causing a substance in solution to be rendered insoluble (Grant & Hackh's Chemical Dictionary, 5th Edition, 1987, p. 470; attached as **Exhibit C**). Instant step 1 involves the formation of a crude ubiquinone-10 solid as a precipitate when the final concentration is 50 to 100 v/v%, and the mixture is at a temperature of 0°C to 30°C. The original solution, therefore, is reduced in volume and cooled, resulting in the precipitation of the crude ubiquinone-10. Therefore the precipitation of crude ubiquinone-10 in instant step 1 is inherently disclosed, since precipitation is what is being described. Instant step 2 involves the recovery of the precipitate or insoluble matter (*i.e.*, crude ubiquinone-10).

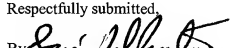
Thus, Applicants further reiterate their previous argument that JP '394 teaches solubulizing a crude ubiquinone-10 extract in hexane, followed by extraction with a 28% NH4OH-MeOH (5:95) solution with the MeOH layer discarded and the hexane layer extracted with 95% MeOH and the MeOH layer discarded. The impurities are removed via washings of the hexane layer with methanol solutions and the purified ubiquinone-10 residing in the hexane layer. The instant invention involves the precipitation of ubiquinone-10 in step [2] and impurities in step [4] from methanol solutions to afford purified ubiquinone-10 in a methanol solution. JP '394 provides no suggestion or motivation to precipitate ubiquinone-10 or impurities from crude solutions of ubiquinone-10 in polar solvents (*i.e.*, methanol). Indeed, JP '394 teaches away from using polar solvents to dissolve ubiquinone-10, since it teaches using hexane which is non-polar. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

In view of the foregoing remarks, applicant believes the pending application is in condition for allowance, and earnestly solicits same. Further, in connection with this filing, the Commissioner is hereby authorized and requested to charge any deficiency in fees, or refund any excess in fees, to Darby and Darby Deposit Account No. 04-0100.

Dated: January 30, 2008

Respectfully submitted,

By 
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